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Federal Agencies

December 15, 2003

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1636**

Re: U.S. Utility Patent Application  
Appl. No. 10/617,377; Filed: July 11, 2003  
For: **Methods for Reducing Adventitious Agents and Toxins and Cell  
Culture Reagents Produced Thereby**  
Inventors: Biddle *et al.*  
Our Ref: 0942.4600003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (6 sheets);
3. First Supplemental Information Disclosure Statement;
4. Listing of the cited documents on Form PTO-1449 (1 sheet);
5. Second Supplemental Information Disclosure Statement;
6. Listing of the cited documents on Form PTO-1449 (5 sheets); and
7. Return postcard.

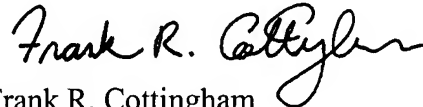
Commissioner for Patents  
December 15, 2003  
Page 2

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

FRC/pcd  
Enclosures

:\ODMA\MHODMA\SKGF\_DC1;209483;1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Biddle *et al.*

Appl. No. 10/617,377

Filed: July 11, 2003

For: **Methods for Reducing  
Adventitious Agents and Toxins  
and Cell Culture Reagents  
Produced Thereby**



Confirmation No. 2241

Art Unit: 1636

Examiner: *To Be Assigned*

Atty. Docket: 0942.4600003/RWE/FRC

Information Disclosure Statement

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

All of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/343,686, filed June 30, 1999, or in Application No. 09/576,900, filed May 23, 2000, which are relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

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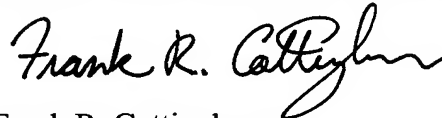
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: DEC. 15, 2003

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(202) 371-2600



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
0942.4600003/RWE/FRCAPPLICATION NO.  
10/617,377APPLICANT  
Biddle et al.FILING DATE  
July 11, 2003GROUP  
1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	3,771,237	11/13/1973	Hansen et al.			04/04/1972
	AB1	4,511,592	04/16/1985	Percel et al.			06/20/1984
	AC1	4,689,297	08/25/1987	Good et al.			03/05/1985
	AD1	4,885,848	12/12/1989	Christensen, M.A.			07/13/1988
	AE1	5,006,204	04/09/1991	Jensen, J.P.			10/31/1988
	AF1	5,133,137	07/28/1992	Petersen, B.M.			02/05/1991
	AG1	5,325,606	07/05/1994	Liborius, E.			12/23/1992
	AH1	5,357,688	10/25/1994	Christensen, M.A.			05/04/1993
	AI1	5,392,531	02/28/1995	Christensen et al.			02/28/1994
	AJ1	5,474,931	12/12/1995	DiSorbo et al.			09/21/1993
	AK1	4,071,412	01/31/1978	Eisenberg et al.			05/05/1975

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	SU 1097253	06/15/1984	Soviet Union			Yes No
	AM1	EP 0 356 071 A2	02/28/1990	Europe			Yes No
	AN1	DK 167090 B1	08/30/1993	Denmark			Yes No
	AO1	WO 95/13867	05/26/1995	WIPO			Yes No
	AP1	WO 98/15297	04/16/1998	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Camire, J.C.F., et al., "Efficient Cultivation of Cells Using Powdered Serum," In Vitro 34:Abstract No. V-1008, Tissue Culture Association (March 1998).
	AS	<u>1</u>	Davis, B., et al., "Sterilization and Disinfection," in Microbiology, Ch. 67, Harper and Row Publishers, Inc., Hagerstown, MD, pp. 1264-1274 (1973).
	AT	<u>1</u>	Downes, T.E.H., et al., "The relative nutritive value of irradiated spray-dried blood powder and heat-sterilized blood meal as measured in combination with whey protein," Suid Afrikaanse Tydskrif Vir Veekunde (S. Afr. J. Anim. Sci.) 17:55-58, Bureau Of Scientific Publications Of The Foundation For Education (1987).

EXAMINER

DATE CONSIDERED

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0942.4600003/RWE/FRC

APPLICATION NO.  
10/617,377

APPLICANT  
Biddle et al.

FILING DATE  
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1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA2	4,490,403	12/25/1984	Pisecky et al.			06/13/1983
	AB2	4,544,637	10/01/1985	Keggins et al.			09/14/1982
	AC2	4,615,978	10/07/1986	Sandine et al.			12/18/1984
	AD2	4,620,908	11/04/1986	Van Duzer, J.P.			06/18/1984
	AE2	4,621,058	11/04/1986	Reddy, M.S.			04/09/1984
	AF2	4,975,246	12/04/1990	Charm, S.			01/23/1989
	AG2	4,999,301	03/12/1991	Bryan-Jones, D.G.			09/27/1988
	AH2	5,366,696	11/22/1994	Williams, M.R.			01/07/1993
	AI2	5,518,709	05/21/1996	Sutton et al.			03/15/1993
	AJ2	5,580,856	12/03/1996	Prestrelski et al.			07/15/1994
	AK2	5,811,406	09/22/1998	Szoka, Jr. et al.			06/09/1995

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Frazier, W.C., et al., "General Principles of Food Preservation: Asepsis, Removal, Anaerobic Conditions," in <i>Food Microbiology</i> , 3 <sup>rd</sup> ed., McGraw-Hill Book Company, New York, NY, pp.93-99, 122-123, 126-127, 143-153, 161, 434-436, 444-445 (1978).
	AS	<u>2</u>	Freshney, R.I., "The Culture Environment: II. Media and Supplements," in <i>Culture of Animal Cells: A Manual of Basic Technique</i> , Alan R. Liss, Inc., New York, NY, pp. 74-78 (1983)
	AT	<u>2</u>	GEA Process Technology Division, Aeromatic-Fielder Division, Columbia, MD, technical brochure entitled "Batch fluid beds: Customized fluid bed systems for solids processing," 8 pages, Bochum, Germany (Date Unknown)

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA3	5,869,321	02/09/1999	Franklin			08/20/1997
	AB						
	AC						
	AD						
	AE						
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	AG						
	AH						
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	AK						

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	GEA Pharmaceutical Processing, Columbia, MD, Marketing brochure entitled "Plant and Process Technology by the GEA Companies," 12 pages (Date unknown)
	AS	<u>3</u>	"Granulated Media," in <i>Microbiology Catalog</i> , EM Science, 2 pages, Cincinnati, Ohio (1999)
	AT	<u>3</u>	Hampel, C., et al., "Sterilization (Industrial)," in <i>The Encyclopedia of Chemistry</i> , Litton Educational Publishing, Inc., New York, NY, pp. 1052-1053 (1973).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Harlow, E., and Lane, D., "Sampling Serum," In: <i>Antibodies: A Laboratory Manual</i> , Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, p.116 (1988).
	AS	<u>4</u>	NIRO, Inc., Technical Bulletin No. 95001 entitled "Fluid Bed Multi-Processor," Aeromatic-Fielder Division, 2 pages, Columbia, MD (1995).
	AT	<u>4</u>	Marketing brochure for EZMix Fermentation Media, Sigma, St. Louis, MO, 2 pages (publication date before October 1996).

EXAMINER

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FORM PTO-1449

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0942.4600003/RWE/FRCAPPLICATION NO.  
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Biddle et al.FILING DATE  
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Reinert, J., et al., "Sterilization," "Culture Media," "Composition of Culture Media," in <i>Plant Cell and Tissue Culture. A Laboratory Manual</i> , Springer-Verlag, Berlin Heidelberg, Germany, pp. 74, 76-77 (1982).
	AS	<u>5</u>	Rohde, B.A., et al., BBL Manual of Products and laboratory Procedures, BBL-Becton Dickinson & Co., Mississauga, Canada, pp. 97, 101, 111, 123 (1973).
	AT	<u>5</u>	Robey, T.E., and Ryan, J.M., "A Comparison of the Effects of Powdered and Liquid Fetal Bovine Serum on Normal Human Cell Growth, Metabolism and Urokinase Formation," <i>In Vitro</i> 34:Abstract No. V-1007, Tissue Culture Association (March 1998).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Dialog File 351, Derwent WPI, Accession No. 76-44200X/197624, English language abstract for Denmark Patent Publication No. DK 167090 B1, Derwent Info Ltd. (1976)
	AS	<u>6</u>	Product and Corporate Information, American Protein Corporation, Ames, IA, < <a href="http://www.AmericanProtein.com/index.html">http://www.AmericanProtein.com/index.html</a> > 44 pages (July 1999).
	AT	<u>6</u>	WIPDS Database on STN, Accession No. 85-005539, English language abstract for Soviet Union Patent Publication No. SU 1097253, Derwent Info Ltd. (1984)

EXAMINER

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Biddle *et al.*

Appl. No. 10/617,377

Filed: July 11, 2003

For: **Methods for Reducing  
Adventitious Agents and  
Toxins and Cell Culture  
Reagents Produced Thereby**



Confirmation No. 2241

Art Unit: 1636

Examiner: *To Be Assigned*

Atty. Docket: 0942.4600003/RWE/FRC

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith, in connection with the above-captioned application.

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Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: DEC. 15, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600



FORM PTO-1449

**FIRST SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**ATTY. DOCKET NO.  
0942.4600003/RWE/FRCAPPLICATION NO.  
10/617,377APPLICANT  
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July 11, 2003GROUP  
1636**U.S. PATENT DOCUMENTS**

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	AA						
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	AC3	5,700,426	12/23/1997	Schmitthaeusler et al.			11/30/1994
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	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

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	AM2	WO 97/42980	11/20/1997	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR		
	AS		
	AT		

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Examiner: *To Be Assigned*

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Documents AO2, AP2, AM3, AN3, AO3, and AP3 are not in the English language. English language abstracts of these documents were submitted as documents AS7, AR10, AS10, AT10, AR11, and AS11, respectively.

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information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Second Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: DEC. 15, 2003

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10/617,377APPLICANT  
Biddle et al.FILING DATE  
July 11, 2003GROUP  
1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
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	AD3	2,835,586	05/20/1958	Peebles, D.D.			07/27/1953
	AE3	4,053,642	10/11/1977	Hup et al.			06/12/1975
	AF3	4,072,570	02/07/1978	Williams, W.			02/20/1976
	AG3	4,073,951	02/14/1978	Sargeant, R.G.			08/25/1976
	AH3	4,820,627	04/11/1989	McGeehan, J.K.			03/24/1986
	AI3	5,155,039	10/13/1992	Chrisope et al.			07/22/1991
	AJ3	5,756,046	05/26/1998	Winks et al.			06/15/1994
	AK3	5,773,279	06/30/1998	Miller et al.			11/27/1996

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN2	GB 1 355 192	06/05/1974	Great Britain			Yes No
	AO2	CS 169,007	06/29/1976	Czechoslovakia			x Yes No
	AP2	JP 51-98354	08/30/1976	Japan			x Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Brock, T.D., et al., "Acidity and pH," in <i>Biology of Microorganisms</i> , 4 <sup>th</sup> edition, Brock, T.D., et al., eds., Prentice-Hall, Englewood Cliffs, NJ, p. 257-260 (1984).
	AS	7	Hana, L., et al., "Preservation of sera, protein fractions, and Tissue cultures media by spray drying," (English language abstract for CS 169,007 (Document No. AO2)), <i>Chem. Abstracts</i> 88: Abstract No. 118718 (1978).
	AT	7	Hay, R., et al., "American Type Culture Collection Catalogue of Cell Lines and Hybridomas," 6 <sup>th</sup> Ed., ATCC, Rockville, MD, p. 347 (1988).

EXAMINER

DATE CONSIDERED

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL3	EP 0 049 632 A2	04/14/1982	Europe			Yes No
	AM3	JP 57-152882	09/21/1982	Japan			x Yes No
	AN3	EP 0 155 427 A1	09/25/1985	Europe			x Yes No
	AO3	JP 1-157395	06/20/1989	Japan			x Yes No
	AP3	JP 4-198137	07/17/1992	Japan			x Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	8	Jensen, J.D., "(Some recent advances in) Agglomerating, Instantizing, and Spray Drying," <i>Food Technol.</i> 29:60-71, Institute of Food Technologists (1975).
	AS	8	Life Technologies, Inc., "GIBCO-BRL 1995-1996 Product Catalogue and Reference Guide," Thomson Print Services Ltd., Glasgow, Scotland, pp. 1-18, 1-24, and 1-7 (1995).
	AT	8	Life Technologies, Inc., "GIBCO-BRL 1996-1997 Catalogue for Cell Culture," Thomson Print Services Ltd., Glasgow, Scotland, p. 16 and p. 56 (1996).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL4	WO 94/27645	12/08/1994	WIPO			Yes No
	AM4	WO 95/00031	01/05/1995	WIPO			Yes No
	AN4	WO 96/23868	08/08/1996	WIPO			Yes No
	AO4	WO 97/11157	03/27/1997	WIPO			Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Life Technologies, Inc., "GIBCO-BRL 1996-1997 Catalogue for Cell Culture," Thomson Print Services Ltd., Glasgow, Scotland, pp. 79-84 (1996).
	AS	2	Pending Non-Provisional United States Patent Application No. 09/606,314, Fike et al., filed June 29, 2000 (NOT PUBLISHED).
	AT	2	Pending Non-Provisional United States Patent Application No. 09/705,940, Fike et al., filed November 6, 2000 (NOT PUBLISHED).

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Derwent World Patent Index, Accession No. 1976-78201X, English language abstract for JP 51-98354 (Document AP2).
	AS	<u>10</u>	Derwent World Patent Index, Accession No. 1982-91800E, English language abstract for JP 57-152882 (Document AM3).
	AT	<u>10</u>	Dialog File 351, Accession No. 4411606, Derwent WPI English language abstract for EP 0 155 427 A1 (Document AN3).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>11</u>	Derwent World Patent Index, Accession No. 1989-218070, English language abstract for JP 1-157395 (Document A03).
AS	<u>11</u>	JPO English language abstract for JP 4-198137 (Document AP3).
AT	<u>11</u>	Supplementary European Search Report for European Application No. EP 98 90 8542, completed September 9, 2002.

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